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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/049,515 | 06/14/2002 | Gregory D. Plowman | 038602-1320 | 4070 |

22428 7590 09/22/2004

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| EXAMINER | |
|---|---|
| GEBREYESUS, KAGNEW H | |
| ART UNIT | PAPER NUMBER |
| 1652 | |

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/049,515 | PLOWMAN ET AL. | |
| | Examiner | Art Unit | |
| | Kagnew H Gebreyesus | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *6-11 and 13-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 July 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## ***DETAILED ACTION***

In response to the restriction, applicant has responded with an election with traverse of Group I, claims 1-5 and claim 12.

Applicant's election with traverse of Group I, Claims 1-5 and 12 on July 02, 2004 is acknowledged. The traversal is on the ground(s):

(1) That unity of inventions principle has been misapplied as there is a "special technical features" defining the inventions of Group I-VII i.e. applicants argue that each of the sequences define a special technical feature linking groups I-VII.

(2) That the claimed sequences share a common utility.

(3) That the search does not cause serious burden for examination.

However this is not found persuasive and each of the issues raised are addressed in greater detail below:

1) Lack of unity: Applicants are in progress in elucidating the potential involvement of each of the 20 dual specificity protein phosphatases in any of the variety of diseases disclosed in the specification. The examiner recognizes that the knowledge gained henceforth will define the specific utility of these protein phosphatases more clearly. However to date none of these phosphatases have been shown to directly be involved in any one of the diseases disclosed in the specification. Any number of other genes including phosphatases could be possible candidates that cause the disorders associated with the chromosome. Applicants have merely mapped 8 out of the 20 genes at a chromosomal region and attributed disease(s) resulting from an aberration in that region to the isolated genes. For instance, chromosomal region 2q33-q37.2 includes the

HER4/ERB4 gene implying that diseases other than diabetes can be associated with this region. However SEQ ID NO: 25 does not encode the HER4/ERB4 gene. Therefore to date the only shared technical feature linking these entities is that they all are presumably dual specificity protein phosphatases. Furthermore dual specificity protein phosphatases of the various kinds mentioned (CDC14, MKP, MTM) are known in the art thus claim 1-5 do not constitute a special technical feature under PCT rule 13.2.

Applicants argument that all the 20 phosphatases are novel dual specificity protein phosphatases and thus constitute a special technical feature is not agreed with as claims 1-5 are directed to a genus of phosphatases in addition to a large number of variants and derivative of these sequences. Therefor the specific sequences cannot be a special technical feature linking all claims as this is not a feature to which all claims are limited. As previously discussed EMBL Accession Nos: AA023073 and AA028820 each teach a variant/derivative of the sequence of SEQ ID NO: 26 as claimed in claim 1 and thus group I-VII are devoid of a special technical feature as defined by PCT rule 13.2.

2) Common Utility: (a) Applicants disclose that the novel dual specificity protein phosphatases have similar utility. However the spec discloses a large number and diverse diseases where the ppases could potentially be involved. Given the large number and variety of ppases in general and the various cellular processes they are involved one can not assume that similarity in structure confers similar utility. b) Even if one assumes common utility of the 20 dual specificity protein phosphatases, the sequences do not share a substantial structural feature disclosed as being essential to that utility as there is no structural feature that must be shares by all variants and derivatives with the scope of claim 1.

3) Given the above facts each sequence has to be thoroughly searched in sequence databases, non-patented and patent databases and the search for eachsequence is independent of the search required for the other which will cause an undue burden for examination. Therefor applicants argument is not found persuasive because while the search necessary for examination of all groups I(a-i)-group IV(a-i) overlaps it is not coextensive and would become undue burden (site MPEP).

Therefore, the requirement is still deemed proper and is therefore made FINAL.

***Priority date for SEQ ID NO: 26***

With regards to the priority date sought by applicant, the examiner did not find a full length sequence of SEQ ID NO: 26 in the provisional application thus the priority date is not acknowledge for this sequence thus the priority date is recognized as August 11, 2000 with regards to SEQ ID NO: 26.

***Note:***

It is noted that applicant refers to kinase and phosphatases interchangeably in their response filed on 07/04/04. As these are different activities which are not associated with thew same proteins, the office requests that applicants review all responses be sure they are referring to the correct activities/proteins.

***Drawings***

1. The drawings are objected to because they are illegible and lack clarity. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is

being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1(c-i), 2-5 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not contain any disclosure of the function of all DNA sequences that can hybridize to SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 38, 40, 42 and variations thereof as defined in parts (d-i) of claim 1. The genus of protein phosphatases comprising the

above sequences encoded by the corresponding nucleic acid sequences is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

3. Claim1-5 and 12 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

4. Claim 1-5 and 12 in part are so broad as to encompass any dual specificity protein kinase that can hybridize to a nucleic acid sequence and variants encoding SEQ ID NO: 26 or to the variants thereof. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of variants broadly encompassed by the claims. Though the specification discloses the possible enablement of SEQ ID NO: 26, a person skilled in the art would not know how to make and use the structural variants of SEQ ID NO: 26. While recombinant and

mutagenesis techniques are known, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired utility are limited in any protein and the result of such modifications is unpredictable.

In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any dual specificity protein phosphatase because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting the utility; (B) the general tolerance of the phosphatase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any domain with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially choices is likely to be successful.

5. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including sequences that hybridize to SEQ ID NO: 26 and variants thereof. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and

improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1(d, f), 5 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. References is made to "any of the figures" in the above claims with regards to domain delimitations of amino acid residues without clearly pointing out the positions being referred to. From this recitation it is unclear what portion of which figure is being refered and thus the scope of the claim is unclear. Applicant is advised to point out the domain delimitations clearly and distinctly, preferably in the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 1 as it pertains to SEQ ID NO: 26 is rejected under 35 U.S.C. 102(e) as being anticipated by SEQ ID NO: 2 in patent US-6,420,153 by Meyers et. al. (priority date of Feb., 29, 2000). Meyers et. al. describe a human dual specificity protein phosphatase gene that encodes a protein having 97.9% sequence identity to SEQ ID NO: 26 at the amino acid level and over 90% identity at the nucleic acid (SEQ ID NO: 25) level of the present application. Thus the gene of Meyers et.al. clearly would hybridize to SEQ ID NO: 25 under high stringency conditions and meets all the limitating conditions of claims 1,3 and 4. The invention in this patent (US 6,420,153) claims isolated nucleic acid molecules that encode dual specificity protein phosphatase family members. In addition the invention teaches recombinant expression vectors (claim 2) and host cells (claim 5 and 12) into which the expression vectors have been transfected. The invention also provides methods of identifying compounds that modulate the phosphatases disclosed (claim 12).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER